

REMARKS

This Amendment, filed in reply to the Office Action dated March 18, 2009, is believed to be fully responsive to each point of objection and rejection raised therein. Accordingly, favorable reconsideration on the merits is respectfully requested.

Claims 1-7 and 9-12 are rejected. Claims 7 and 10-12 are canceled herewith without prejudice or disclaimer. Claims 1, 3-6 and 9 are amended herewith to improve clarity and to delete non-elected subject matter. Claims 5 and 6 are also amended herewith to be properly multiply dependent. Accordingly, new Claims 13-15 are introduced to capture subject matter canceled from Claims 5 and 6 (*i.e.*, to the extent that Claims 5 and 6 depend from Claim 4). Support for new Claims 13 and 14 can be found in original Claims 5 and 6. Support for new Claim 15 can be found in original Claim 9.

Applicants also correct herewith a self-evident typographical error in Table 3 of Example 5 of the specification as filed. One of skill in the art would have recognized the existence of the error in SEQ ID NO: 20 in Table 3 in the specification, and would have recognized the appropriate correction, in view of SEQ ID NO: 3 in the sequence listing as originally filed (and recited on page 1, line 30, and in Claim 1 of the specification as originally filed). This is because SEQ ID NO: 3 encompasses, in substantial part, the sequence of SEQ ID NO: 20. Further, because SEQ ID NO: 20 and SEQ ID NO: 21 hybridize to form a double-stranded siRNA (which ds-siRNA is used in the experiments depicted in Table 3), and because the typographical error in SEQ ID NO: 20 occurs within the stretch of complementary nucleotides, one of skill in the art would instantly have recognized the existence of the error in the complementary sequence in SEQ ID NO: 21, and would have recognized the appropriate correction therefor.

No new matter is added by way of this amendment. Entry and consideration of this amendment are respectfully requested.

Priority

Applicants thank the Examiner for acknowledging Applicants' claim to foreign priority, and for acknowledging receipt of a certified copy of Applicants' foreign priority document, namely Chinese Application No. 02156785.9.

Restriction Requirement

On page 2 of the Office Action, the Examiner maintains the Restriction Requirement. Although the Examiner acknowledges Applicants' traversal arguments, namely that the improper legal standard was applied because the instant Application is a National Stage filing of an International Application under 35 U.S.C. § 371, and thus Restriction is governed by Unity of Invention practice under PCT Rule 13, the Examiner states that “[c]ontrary to Applicants' assertions, the instant sequences are chemically, functionally, and structurally distinct ... and thus are distinct inventions ... [A] search of one sequence would not be coextensive with the searches required for each of the other sequences. For these reasons, as well as the undue search burden ... the restriction is hereby maintained.” Accordingly, the Examiner requests that the claims be amended to remove non-elected subject matter.

Whilst Applicants strongly disagree with the rationale employed in maintaining the Restriction, solely in the interest of compacting prosecution, and in no way acquiescing to the merits of the Restriction, Applicants herewith amend the relevant claims to remove non-elected

subject matter. Applicants reserve the right to pursue this canceled subject matter in one or more Divisional Applications under the protection of 35 U.S.C. § 121.

Claims 1-7 and 9-12 are Adequately Described Under 35 U.S.C. § 112, first paragraph

On page 3 of the Office Action, Claims 1-7 and 9-12 are rejected under 35 U.S.C. § 112, first paragraph, as allegedly lacking an adequate written description.

In making the rejection, the Examiner contends that the disclosure as filed does not adequately describe the structural features or elements of the claimed genus of inhibitory RNAs. Specifically, the Examiner contends that the claims are directed to a subgenus of inhibitory RNA molecule (or DNA or vector based thereon), defined according to functional properties, *i.e.*, anti-HIV infection activity, and prevention and treatment of AIDS. The Examiner acknowledges that the specification as filed discloses *in vitro* experiments demonstrating inhibition of expression of HIV *env* using siRNA. However, the Examiner appears to contend that the specification does not demonstrate that SEQ ID NO: 3, or a fragment thereof, possesses the recited activity, and as a result, one of skill in the art would have been unable to predict which fragments of SEQ ID NO: 3 would possess the recited anti-HIV infection activity.

Applicants respectfully disagree, and traverse the rejection in view of the following remarks.

Initially, Applicants respectfully point out that Claims 7 and 10-12 are canceled herewith without prejudice or disclaimer, mooting the rejection of these claims.

Regarding Claims 1-6 and 9, Applicants respectfully point out that the preambles of Claims 1, 4, 5, 6 and 9 have been amended to remove the recitation that the claimed RNA (or DNA, expression vector, or liposome based thereon) “demonstrates anti-HIV infection activity

and is employed in prevention and treatment of AIDS.” Accordingly, the claims as amended are not directed to a subgenus of inhibitory RNA molecule (or DNA, vector or liposome based thereon) defined by function, *i.e.*, which demonstrate anti-HIV infection activity, but rather, are directed to a genus of single- or double-stranded RNA molecule (or DNA, vector or liposome based thereon) comprising SEQ ID NO: 3, or comprising a fragment of SEQ ID NO: 3 that is 19-28 nucleotides in length.

To comply with the written description requirement of §112, first paragraph, all that is required is that one of skill in the art would have *reasonably concluded* that Applicants were in possession of what is claimed. See *Moba, B.V. v. Diamond Automation, Inc.*, 325 F.3d 1306, 1319, 66 USPQ2d 1429, 1438 (Fed. Cir. 2003). Applicants respectfully submit that one of skill in the art would have understood Applicants to be in possession of the genus of single- or double-stranded RNA molecules (or DNA, vector or liposome based thereon) comprising SEQ ID NO: 3, or which comprise a fragment of SEQ ID NO: 3 that is 19-28 nucleotides in length, because the precise structure of SEQ ID NO: 3 is expressly disclosed in the specification as originally filed. See page 1, line 30. One of skill in the art, using the simplest of computer algorithms, or merely by visualizing SEQ ID NO: 3, could readily envisage the identity of every possible 19-28 nucleotide fragment within SEQ ID NO: 3, and thus would have recognized that Applicants were in possession of every species, and thus the genus, of 19-28 nucleotide fragments of SEQ ID NO: 3. Accordingly, one of skill in the art would have recognized Applicants to be in possession of the claimed subject matter. The adequacy of the written description in the specification as to which residues or domains of SEQ ID NO: 3 are important for, or what fragments of SEQ ID NO: 3 would possess, anti-HIV infection activity, is irrelevant to the claims as amended.

Further, Applicants respectfully refer the Examiner to the revised Written Description Guidelines published in 2008, in particular to Example 11, which pertains to assessing adequacy of written description for claims to genera of polynucleotides or polypeptides. In a hypothetical example provided by the Office, which is relevant to the facts in the instant case, an Application contains claims to polynucleotides having at least 85% sequence identity to a known polynucleotide sequence (*i.e.*, it encompasses a variety of fragments, so long as they have 85% identity), with and without a recited function. In the hypothetical claim which does not recite the function, the Office notes that with the aid of a computer, one of skill in the art could have identified all of the nucleic acids that encode a polypeptide with “at least 85% sequence identity” to the disclosed sequence, and thus the written description requirement is met.

In view of the above, Applicants respectfully submit that one of skill in the art would have understood Applicants to be in possession of the claimed subject matter, and thus the written description requirement is met.

Withdrawal of the rejection is respectfully requested.

The Enablement Rejection of Claims 10-12 is Moot

On page 5 of the Office Action, Claims 10-12 are rejected under 35 U.S.C. § 112, first paragraph, as allegedly lacking enablement.

Applicants note that Claims 10-12 are canceled herewith, without prejudice or disclaimer, mooting the rejection.

Withdrawal of the rejection is respectfully requested.

Conclusion

In view of the above, reconsideration and allowance of this application are now believed to be in order, and such actions are hereby solicited. If any points remain in issue which the Examiner feels may be best resolved through a personal or telephone interview, the Examiner is kindly requested to contact the undersigned at the telephone number listed below.

The USPTO is directed and authorized to charge all required fees, except for the Issue Fee and the Publication Fee, to Deposit Account No. 19-4880. Please also credit any overpayments to said Deposit Account.

Respectfully submitted,



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